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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,834	04/04/2002	Jeremy Marshall	3003-1010	5293

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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/089,834

Applicant(s)

MARSHALL ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 first states that the first abutment includes both ribs (7 and 8) in lines 4-5. Claim 10 goes on to define the second abutment as being one of the ribs (8). These limitations are contradictory.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,324,303 (Strong et al.) in view of US Patent No. 3,651,972 (Itoh).

Strong discloses lancet with a cap. As best shown in Figure 3, the cap (5) is integrally formed with the lancet body (3) at connection piece (11), or "neck." Strong explains that the cap and lancet are integrally molded of plastic material (column 6, lines 44-46). The cap is designed to be detachable from the lancet body by twisting and pulling, so that the piece (11) will break at section (23) (column 6, lines 44-54).

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The cap conceals the needle tip (7) before removal, as in Figures 3 and 4, and then is connected to the lancet so that the needle (7) can momentarily pass through a central aperture (17), as in Figure 9C. The cap includes inwardly projecting lugs (29) that are adapted to engage "abutments" defined on either side of a groove (25,27) on the lancet body (3) (column 6, lines 60-65 and column 7, lines 5-15) when both are removed from the firing device, as illustrated in Figure 9e. As shown in Figure 3, the cap has a reduced diameter at the site of the lugs in a relaxed state, so that the lugs (29) will engage a groove in the lancet body when the cap is removed from the firing device. Since the cap is resilient, the diameter of the cap at the site of the lugs (29) increases to fit over the circular end of the firing device. The lancet body includes projections (13,14) that prevent it from rotating relative to the firing device (column 6, lines 1-5). The projections (13,14) are arranged to provide the lancet body with a cruciform cross-sectional shape.

Strong fails to form the cap to have an elliptical cross section at the site of the lugs. Itoh discloses another resilient cap (104) in Figure 6 that includes a connection means (111) on the inside surface that interlocks with another device (101). The opening of the cap has an elliptical cross section, as shown in Figure 7, and the connection means are located on its minor axis. Itoh explains that the cap is squeezed along the major axis (P in Figure 10) to deform the cap to a more circular shape and disengage the connection means from the device (101). The caps of Strong and Itoh have connection means on their inside surfaces and resilient structural characteristics that allow a user to engage and disengage the connection means with another device. Since these caps are functionally equivalent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the cap of Strong

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to have an elliptical cross section. Forming the cap of Strong to have an elliptical cross section at the site of the lugs would allow the cap to perform as recited in the claims.

Regarding claims 9,10, and 12-15:

The claims require the first abutment to be a gap between two circular ribs that have a greater diameter than that of the lancet body. Strong, as modified by Itoh above, fails to meet this requirement and forms the “first abutment” as a groove in the lancet body. At the time the invention was made, it would have been an obvious matter of design choice to one of ordinary skill in the art to form the groove of the modified Strong cap to lie between two outwardly projecting ribs, because applicant has not disclosed that the ribs solve any stated problem or have a particular advantage over the prior art. One of ordinary skill in the art, furthermore, would have expected applicant’s invention to perform equally with the groove of Strong instead of the ribs, because the two structures perform the same function of interlocking with lugs on the cap to retain the lancet.

Strong and Itoh also fail to include two opposed slots (15) on the cap. At the time the invention was made, it would have been an obvious matter of design choice to one of ordinary skill in the art to include slots in the surface of the modified Strong cap, because applicant has not disclosed that these slots are used for a particular purpose, solve any stated problem, or have a particular advantage over the prior art. One of ordinary skill in the art, further more, would have expected applicant’s invention to perform equally without the slots, because this structural feature does not perform a function.

### ***Response to Arguments***

3. Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. Applicant argues that the elliptical cross-sectional shape of a cap is non-obvious and that other non-specified structural features of the claims are non-obvious. Strong discloses a lancet and cap system that functions essentially the same as applicant's device. The cap is integrally formed with the lancet body, breaks off, resiliently deforms to attach to a firing device, and then resumes a compressed diameter shape to engage inwardly projecting lugs with a groove on a lancet body as it is removed from the firing device. Itoh is relied upon for teaching a cap with an elliptical cross-section that deforms to disengage/engage connection means on its inner surface at the minor axis with another device. Itoh clearly shows in Figure 7 that a connection means should be located on the minor axis of an elliptical cap. The elliptical cap of Itoh is capable of being pressed into a circular shape so that it can be fitted over a circular body. All the main structural and functional components are disclosed by the prior art. There are several features in the claims that are considered to be obvious matters of design choice, as discussed in more detail above, such as slots on the outer surface of the cap and ribs that define a groove between them. Since the slots do not perform a function, and the ribs are simply another way to form a groove, these features are not considered to be patentable over prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW  
11/17/05

SKW

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
11/27/05